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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,713	07/08/1999	HERWIG BUCHHOLZ	MERCK-1900	7039

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT.	PAPER NUMBER
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1617

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/349,713

Applicant(s)

BUCHHOLZ ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-14, 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14, 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on February 20, 2003 has been entered. Claims 1-10, 12-14, 26 are pending. Any rejection that is not addressed here are considered obviated in view of the amendments.

Examiner also requests Applicant to provide a copy of all pending claims in response to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claims 1-10, 12-14, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of "contains essentially no flavones, flavonoids or glycosides thereof other isoquercitrin or the above listed componenets" which renders the claim ambiguous. It is not clear what is the scope of this limitation. Specifically, what would be construed as "essentially no flavone or flavonids." The specification further fails to describe or objectively quantify this limitation. Therefore, the metes and bounds of the claims are not clear.

Claims 1-6, 8, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawruk US Patent 5,478,579.

Sawruk discloses compositions for enhancing absorption of calcium into bones comprising at least one flavonol aglycone glycoside selected from the group consisting

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of isoquercitrin, quercetin, kaemferol and myricetin (see abstract; col 2, lines 65-67, claims 6-7, 15). Sawruk further teaches amounts of isoquercetin in ranges that overlap with the instantly claimed ranges; therefore, Sawruk's isoquercetin provides antiviral activity (see col 4, lines 45-52). In example 1, the amount of isoquercetin is about 18% of the composition ($125/700 \times 100 = 18$ percent). Sawruk fails to explicitly teach a composition comprising isoquercitrin and quercetin or kaemferol.

It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069(CCPA) 1980. Thus, claims that require no more than mixing together of two conventional compounds used for the same purpose would be *prima facie* obvious. In the instant case, Sawruk teaches the usefulness of isoquercitrin and kaemferol or quercetin for enhancing bone absorption. Therefore, formulating a composition that comprises a combination of isoquercitrin and a second flavone such as quercetin, kaemferol or myricetin would have been *prima facie* obvious.

Claims 1-10, 12-14, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawruk US Patent 5,478,579 in view of Lanzedorfer et al WO 96/18381, Fujirebio et al JP 04234320 ("JP '320") and Bean US Patent 4,132,782 ("Bean").

As argued above, Sawruk is primarily used to show oral compositions containing combination of two flavones, wherein one is isoquercitrin (see abstract, claim 15).

Sawruk does not teach doses of isoquercitrin as an antiviral agent nor does it explicitly teach topical formulation of isoquercitrin.

Lanzendorfer is used to show that conventional nature of art in combining flavones in oral and topical compositions. Lanzendorfer discloses topical and oral flavonoid containing compositions comprising various vitamins, UVB or UVA filters and at least one flavone including quecertin and isoquecertin derivatives. Given the fact that isoquecertin is one of the four subspecies of quecertin, the teachings of Lanzendorfer also encompass utility of isoquecertin. Lanzendorfer also indicates antiviral activity with his composition (see abstract, page 3-5, 43, 54-60, claims 1-7, and examples, example 27 is an oral preparation). Lanzendorfer does not specifically teach antiviral formulations.

JP '320 and Bean are collectively used to show the antiviral activity of isoquercitrin and suitable doses thereof. JP '320 teaches effective doses of isoquercitrin for treatment Hepatitis B Virus (HBV) (see abstract). Bean is also used to show the effectiveness of topical isoquercitrin against herpes simplex virus and useful doses thereof. (see abstract, col 2, lines 15-20). JP '320 and Bean do explicitly teach isoquercitrin compositions with a vitamin or a UV filter.

The teachings of Sawruk, JP 320, Bean and Lanzendorfer are analogous because they all teach various compositions and utilities of flavones containing compositions.

Although Sawruk does not teach topical compositions of isoquercitrin containing a UV filter, it would have been obvious to one of ordinary skill in the art at the time of

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invention to use the teachings of Lanzendorfer and modify the isoquercitrin formulations of Seito for the purposes of preparing a topical composition of isoquercitrin with a UV filter, because as taught by Lanzendorfer preparing such topical formulations of flavones is conventional, and one of ordinary skill in the art would have been motivated to formulate topical formulations to reduce systemic side effects.

Further, it would have been obvious to one of ordinary skill in the art at the time of invention to use such compositions for their anti-viral activity, since as taught by JP '320 and Bean, it was well known in the art that isoquercitrin has antiviral activity against various species of viruses including herpes simplex virus.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
April 25, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200